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10/753,871	01/09/2004	Jenny E. Freeman	8118.003 USDV	6113
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JAMES REMENICK NOVAK DRUCE & QUIGG, LLP 1300 I STREET NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005				
EXAMINER				
CWERN, JONATHAN				
ART UNIT		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/753,871

**Applicant(s)**

FREEMAN ET AL.

**Examiner**

Jonathan G. Cwern

**Art Unit**

3737

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-45, 47-51 and 53-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-45, 66-78, and 81 is/are rejected.
- 7) ☒ Claim(s) 47-51, 53-65, 79 and 80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/9/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

The disclosure is objected to because of the following informalities: On page 1, the status of related applications should be updated. On page 14, line 15, "proximal end 20" should be changed to "proximal end 26".

Appropriate correction is required.

### ***Claim Objections***

Claims 1-5, 7-42, 47-51, 53-65, 73, and 76-80 are objected to because of the following informalities:

In claim 1, line 6, and in claim 47, line 5, "an conductive core" should be changed to "a conductive core".

Claims 10, 38, 47, and 58 contain improper means plus function language.

In claim 24, line 7 and in claim 31, line 5, "said distal collection end" should be plural if referring to the plurality of fibers.

In claim 26, "proximal end" should be plural if referring to the plurality of fibers.

In claim 50, "the step of distending the surface" lacks antecedent basis.

In claims 57 and 65, "the step of inserting" lacks antecedent basis.

In claim 63, in the phrase "disposed on a said sheath", remove the word "a".

Claim 73 is confusing. A tissue surface will inherently be on tissue. It is unclear what an opposing surface is, and where the surface is in relation to the tissue surface being analyzed. Also, "the step of providing a source" and "the step of collecting the radiation transmitted through the tissue" lack antecedent basis.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 7-42, 74-78, and 81 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Because the "surface of interest" is tissue, a part of the body is claimed, which is non-statutory subject matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 66-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Kittrell et al. (US 5106387).

Kittrell et al. show a collection fiber with a conductive core (column 7-column 8), a sheath (column 7-8), an anchoring balloon (column 16, lines 55-column 17, line 5, Figure 17), a second balloon (column 10, line 65-column 11, line 15, also see column 14, lines 40-50), a spectrometer with a detector (column 19), an optical coupler with a lens (column 19), an illumination fiber (column 19), the fibers being flexible (column 4,

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lines 40-55), means to orient the fibers in different directions (column 10, lines 15-50), controlling the orientation of the light (column 13, line 60-column 14, line 25), a toroidal shaped balloon (column 14, lines 40-50, also column 16, lines 55-column 17, line 5, and Figure 17, and 7e), coating the balloon (column 11, lines 15-35), using the system to form an image to be displayed (column 19), and having the catheter be of a sufficient size to be inserted into human blood vessels (column 9, lines 40-55, and Figure 4).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al. (US 5106387) in view of Mersch (US 5776129).

Kittrell et al. show a collection fiber with a conductive core (column 7-column 8), a sheath (column 7-8), an anchoring balloon (column 16, lines 55-column 17, line 5, Figure 17), a second balloon (column 10, line 65-column 11, line 15, also see column 14, lines 40-50), a spectrometer with a detector (column 19), an optical coupler with a lens (column 19), an illumination fiber (column 19), the fibers being flexible (column 4, lines 40-55), means to orient the fibers in different directions (column 10, lines 15-50), controlling the orientation of the light (column 13, line 60-column 14, line 25), a toroidal shaped balloon (column 14, lines 40-50, also column 16, lines 55-column 17, line 5, and Figure 17, and 7e), coating the balloon (column 11, lines 15-35), using the system to form an image to be displayed (column 19), and having the catheter be of a sufficient size to be inserted into human blood vessels (column 9, lines 40-55, and Figure 4). Kittrell et al. fail to show the fibers on the outside of the balloon.

Mersch discloses an endometrial ablation apparatus and method. Mersch teaches that optical fibers can be arranged on the outside of a balloon (abstract).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have arranged optical fibers on the outside of the balloon as taught by Mersch, in the device of Kittrell et al. Such an arrangement would allow the optical fibers to be repositioned.

Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al. (US 5106387) in view of Fox et al. (US 5395361).

Kittrell et al. show a collection fiber with a conductive core (column 7-column 8), a sheath (column 7-8), an anchoring balloon (column 16, lines 55-column 17, line 5, Figure 17), a second balloon (column 10, line 65-column 11, line 15, also see column 14, lines 40-50), a spectrometer with a detector (column 19), an optical coupler with a lens (column 19), an illumination fiber (column 19), the fibers being flexible (column 4, lines 40-55), means to orient the fibers in different directions (column 10, lines 15-50), controlling the orientation of the light (column 13, line 60-column 14, line 25), a toroidal shaped balloon (column 14, lines 40-50, also column 16, lines 55-column 17, line 5, and Figure 17, and 7e), coating the balloon (column 11, lines 15-35), using the system to form an image to be displayed (column 19), and having the catheter be of a sufficient size to be inserted into human blood vessels (column 9, lines 40-55, and Figure 4). Kittrell et al. fail to show the fibers on the outside of the balloon.

Fox et al. disclose an expandable fiberoptic catheter and method of intraluminal laser transmission. Fox et al. teach that a balloon can be arranged inside of the catheter. The fibers are attached to the outer wall of the balloon, and the balloon is then inflated/deflated to adjust the position of the fibers. In this case, the balloon acts to anchor the fibers in place.

It would have been obvious to one of ordinary skill in the art, to have arranged the fibers on the outside of a balloon as taught by Fox et al., in the device of Kittrell et al. Such an arrangement would allow the optical fibers to be repositioned.

### ***Response to Arguments***

Applicant's arguments filed 2/25/08 have been fully considered but they are not persuasive. The applicant has not amended independent claim 66 to recite direct contact, either directly or through the balloon wall, of the distal end of the collection fiber of the probe with the area of interest. The applicant has made no other arguments regarding the claims, and thus the rejection of claims 66-73 is maintained.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is



(571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/  
Examiner, Art Unit 3737

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737